



NOV 17 1994

Re: Reality™ Female Condom
Docket No. 93E-0268

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 4,976,273 filed by Chartex International Plc under 35 U.S.C. § 156. The patent claims the medical device Reality™ Female Condom, PMA P910064.

In the May 11, 1994 issue of the Federal Register (59 Fed. Reg. 24,449), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before November 7, 1994, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Paul Grandinetti, Esq.
Levy, Zito & Grandinetti
1910 K Street N.W., Suite 411
Washington, D.C. 20006

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April 4, 1995

VIA FIRST CLASS MAIL

Mr. Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs
Food and Drug Administration
Rockville, Maryland 20857

Re: Reality™ Female Condom
Patent Term Extension
U.S. Patent No. 4,976,273
Our Ref.: CTX001US
Your Ref.: Docket No. 93E-
0268

Dear Mr. Wilson:

We represent Chartex International Plc, the assignee for the above-identified application for patent term extension.

Please note our new address. Our telephone and facsimile numbers remain the same.

If you have any questions or comments, please do not hesitate to contact us.

Sincerely yours,



Paul Grandinetti

PG:pb

cc: Mr. Stephen G. Kunin,
Deputy Assistant Commissioner
of Patent Policy and Projects
Ms. C. Gibson, Chartex International Plc

OFFICE OF THE ASSISTANT
COMMISSIONER FOR PATENTS

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